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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,546	04/23/2001	William M. Hammesfahr	003BUS	6691

22497 7590 10/31/2006

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EXAMINER	
JAWORSKI, FRANCIS J	

ART UNIT	PAPER NUMBER
3768	

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,546	HAMMESFAHR	
	Examiner	Art Unit	
	Jaworski Francis J.	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 – 44 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant is claiming a Doppler bloodflow cerebral vasospasm detection device in conjunction with a device which in addition to being adjustable in rate responsive to the bloodflow detection acts 'to substitute another medicine' to mitigate the condition. It appears that such is more properly attributable to a clinical decision made by a practitioner as opposed to a functionality of a dosing device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38-44 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al (US4650484) in view of Stanley et al (US4885173), further in view of Fung et al (US5278192), further in view of Ragauskas et al (US5388583).

Shaw et al as noted earlier in relation to claims now cancelled is directed to a transdermal delivery system which provides a daily 24 hour vasodilator dosage (col. 4 lines 7 – 11) at a rate of about 10 – 400 micrograms of vasodilator per hour (col. 4 lines 50 – 52) which is equivalent to 240 – 9600 micrograms per day or .24 – 9.6 milligrams per day total dosage.

Shaw et al defines such vasodilators to include a wide variety of organic nitrates and nitrites (col. 2 lines 35 – 50). Shaw et al do not discuss adaptability for vasospasm treatment or suggest the practice of dosage tapering. It would have been obvious however in view of Stanley et al to adapt the vasodilator delivery system of Shaw et al to use the organic nitrates to treat vasospasm since col. 3 lines 1 – 20 of Stanley et al which effectively merely serves as a pharmacologic teaching notes that this class of vasodilators like the calcium channel blockers have use in treating vasospasm and this pathology may be a varying component of angina towards the treatment of which such a drug would be transdermally directed, irrespective of the fact that Stanley et al in and of itself shows preference for a sustained oral (lollipop) delivery vehicle versus transdermal use. It would have been further obvious in view of Fung et al which although directed to treatment of congestive heart failure nonetheless teaches that when vasodilators such as organic nitrates or nitrites are used for continuous 24 hour transdermal patch therapy in amounts including those suggested by Shaw et al (in Fung et al amounts of 1 – 100mg/day are used, see col. 12 lines 13-18), side effects as well as tolerance quickly develope when dosages exceeding the minimum effective dose are provided and so specific suggestion is made regarding tapering usages towards titration of dose both

upwards and downwards in dosage levels in order to set the final dosage, see page 6 lines 20-47 and page 12 lines 50-58. It would have been inherently obvious to include instructions to a physician or patient for using such potent pharmacologic agents which identify the dosage and taper issues in relation to the specific vascular problem which is being treated, whether the malady is labeled via DRG grouping or other nomenclature

Cardiovascular illnesses such as vasospasticity/ vasoocclusion are commonly considered to be systemic disorders.

The former are applied as discussed in relation to the preceding claims. These references taken together teach that a titrated organic nitrite or nitrate drug regimen e.g. nitroglycerin transdermal patch application in a very low milligram range of daily dosage delivery will treat vasospastic disorders however side-effects such as hypotension mimicking cerebral ischemia may occur, see Jung et al col. 6 lines 38 – 41. It would have been obvious therefore in view of Ragauskas et al col. 3 lines 24 – 39 to evaluate cerebral ischemia including for vasospastic flow measuring probe such that one would be able to diagnose cerebral ischemia due to the vasodilators in use versus cerebral disease due to local vasospasm or due to a common arteriosclerotic process. Note further that all claims of this set do not exclude that the vasodilator may in fact be primarily treating vasospasm elsewhere than in within the cranium, hence the breadth of claiming tends to strengthen the rejection argument. The substitution of medicines when a particular regimen is not working would have been a well-known matter of design to a pharmacologic artisan.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

Francis J. Jaworski
Primary Examiner

FJJ:fjj

10-28-06